

Attorney Docket No. 9050-0053
Serial No. 09/919,471

LISTING OF THE CLAIMS

This Listing of the Claims replaces all prior versions and listings of the claims for this application.

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1. (Currently amended) A method for enhancing sexual desire and responsiveness in a female individual, comprising: (a) orally administering a therapeutically effective amount of an orally active androgenic agent as a first active agent; and ~~optionally~~ (b) administering to the individual a therapeutically effective amount of a second active agent selected from the group consisting of ~~vasoactive agents~~, rho kinase inhibitors, melanocortin peptides, endothelin antagonists, growth factors ~~and other peptidyl drugs~~, cytokines, selective androgen receptor modulators (SARMs), neuropeptides, amino acids, ~~serotonin agonists~~, serotonin antagonists, dopamine antagonists, ~~calcium channel blockers~~, potassium channel openers, potassium channel blockers, non-androgenic steroids, and combinations thereof, wherein administration is on an as-needed basis.

2. (Original) The method of claim 1, wherein the androgenic agent is contained within an oral dosage form.

3. (Original) The method of claim 2, wherein the pharmaceutical formulation is comprised of an immediate release dosage form, and the androgenic agent is administered about 0.25 to 72 hours prior to sexual activity.

4. (Original) The method of claim 3, wherein the androgenic agent is administered about 0.5 to 48 hours prior to anticipated sexual activity.

5. (Original) The method of claim 4, wherein the androgenic agent is administered about 1 to 24 hours prior to anticipated sexual activity.

6. (Original) The method of claim 5, wherein the androgenic agent is administered about 1 to 12 hours prior to anticipated sexual activity.

7. (Original) The method of claim 6, wherein the androgenic agent is administered about 1 to 4 hours prior to anticipated sexual activity.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

8. (Original) The method of claim 2, wherein the pharmaceutical formulation is comprised of a sustained release dosage form.

B2
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9. (Original) The method of claim 8, wherein following administration, the sustained release dosage form provides release of the androgenic agent over a drug delivery period in the range of about 4 to 72 hours.

10. (Original) The method of claim 9, wherein the drug delivery period is in the range of about 4 to 48 hours.

11. (Original) The method of claim 10, wherein the drug delivery period is in the range of about 4 to 24 hours.

12. (Original) The method of claim 2 wherein the androgenic agent is selected from the group consisting of orally active testosterone esters, orally active dihydrotestosterone esters, methyl testosterone, dehydroepiandrosterone, and combinations thereof.

13. (Withdrawn) The method of claim 12, wherein the androgenic agent is an orally active testosterone ester.

14. (Withdrawn) The method of claim 13, wherein the orally active testosterone ester is selected from the group consisting of testosterone propionate, testosterone undecanoate, and testosterone C₄-C₆ alkyl-substituted cycloalkylcarboxylates.

15. (Withdrawn) The method of claim 14, wherein the orally active testosterone ester is testosterone propionate.

16. (Original) The method of claim 12, wherein the androgenic agent is an orally active dihydrotestosterone ester.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

17. (Original) The method of claim 16, wherein the orally active dihydrotestosterone ester is selected from the group consisting of dihydrotestosterone propionate, dihydrotestosterone undecanoate, and dihydrotestosterone C₄-C₆ alkyl-substituted cycloalkylcarboxylates.

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18. (Original) The method of claim 17, wherein the orally active dihydrotestosterone ester is dihydrotestosterone propionate.

19. (Withdrawn) The method of claim 12, wherein the androgenic agent is selected from the group consisting of testosterone decanoate, testosterone pentadecanoate, testosterone undecanoate, testosterone pelargonate, testosterone tridecanoate, testosterone palmitate, testosterone caprate, testosterone isocaprate, testosterone α -methylcaprate, testosterone β -methylcaprate, testosterone laurate, testosterone α -methylpelargonate, testosterone β -methylpelargonate, testosterone β , β -dimethylpelargonate, testosterone β -(p-methyl-cyclohexyl)propionate, testosterone β -(p-ethyl-cyclohexyl)-propionate, testosterone β -(cycloheptyl)-propionate, testosterone α -methyl- β -cyclohexyl propionate, testosterone β -methyl- β -cyclohexyl propionate, testosterone cyclododecylcarboxylate, testosterone adamantine-1'-carboxylate, testosterone adamant-1'-yl-acetate, testosterone methyl- β -cyclohexyl propionate, testosterone β -(bicyclo-[2,2,2-oct-1'-yl])-propionate, dihydrotestosterone decanoate, dihydrotestosterone pentadecanoate, dihydrotestosterone undecanoate, dihydrotestosterone pelargonate, dihydrotestosterone tridecanoate, dihydrotestosterone palmitate, dihydrotestosterone caprate, dihydrotestosterone isocaprate, dihydrotestosterone α -methylcaprate, dihydrotestosterone β -methylcaprate, dihydrotestosterone laurate, dihydrotestosterone α -methylpelargonate, dihydrotestosterone β -methylpelargonate, dihydrotestosterone β , β -dimethylpelargonate, dihydrotestosterone β -(p-methyl-cyclohexyl)propionate, dihydrotestosterone β -(β -ethyl-cyclohexyl)-propionate, dihydrotestosterone β -(cycloheptyl)-propionate, dihydrotestosterone α -methyl- β -cyclohexyl propionate, dihydrotestosterone β -methyl- β -cyclohexyl propionate, dihydrotestosterone cyclododecylcarboxylate, dihydrotestosterone adamantine-1'-carboxylate, dihydrotestosterone adamant-1'-yl-acetate, dihydrotestosterone methyl- β -cyclohexyl propionate, dihydrotestosterone β -(bicyclo-[2,2,2-oct-1'-yl])-propionate, and combinations thereof.

20. (Original) The method of claim 19, wherein the dosage form further includes a lipoidal carrier effective to enhance the oral bioavailability of the androgenic agent.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

21. (Original) The method of claim 1, wherein the therapeutically effective amount is in the range of about 1 μ g to about 250 mg.

22. (Original) The method of claim 21, wherein the therapeutically effective amount is in the range of about 1 μ g to about 150 mg.

23. (Original) The method of claim 22, wherein the therapeutically effective amount is in the range of about 10 μ g to about 100 mg.

24. (Original) The method of claim 2, wherein the therapeutically effective amount of the androgenic agent in the dosage form is a unit dosage.

25. (Canceled)

26. (Currently amended) The method of claim ~~25~~ 1, wherein the second active agent is administered with the androgenic agent.

27. (Currently amended) The method of claim ~~25~~ 1, wherein the second active agent is administered prior to administration of the androgenic agent.

28. (Currently amended) The method of claim ~~25~~ 1, wherein the second active agent is administered after administration of the androgenic agent.

29. (Canceled)

30. (Currently amended) The method of claim ~~29~~ 59, wherein the vasoactive agent is a vasodilator.

31. (Original) The method of claim 30, wherein the vasodilator is selected from the group consisting of vasoactive prostaglandins, endothelin-derived relaxation factors, vasoactive intestinal polypeptide agonists, smooth muscle relaxants, leukotriene inhibitors, and pharmacologically active salts, esters, prodrugs, and metabolites thereof, and combinations of any of the foregoing.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

32. (Original) The method of claim 31, wherein the vasodilator is a vasoactive prostaglandin.

33. (Original) The method of claim 32, wherein the vasoactive prostaglandin is selected from the group consisting of naturally occurring prostaglandins, semisynthetic prostaglandins, synthetic prostaglandins, and pharmaceutically acceptable, pharmacologically active salts, esters, amides, inclusion complexes, prodrugs, metabolites, and analogs thereof, and combinations of any of the foregoing.

34. (Original) The method of claim 33, wherein the vasoactive prostaglandin is selected from the group consisting of naturally occurring prostaglandins and hydrolyzable lower alkyl esters thereof.

35. (Original) The method of claim 34, wherein the vasoactive prostaglandin is selected from the group consisting of PGE₀, PGE₁, 19-hydroxy-PGE₁, PGE₂, 19-hydroxy-PGE₂, PGA₁, 19-hydroxy-PGA₁, PGA₂, 19-hydroxy-PGA₂, PGB₁, 19-hydroxy-PGB₁, PGB₂, 19-hydroxy-PGB₂, PGB₃, PGD₂, PGF_{1α}, PGF_{2α}, PGE₃, PGF_{3α}, PGI₂, and hydrolyzable lower alkyl esters thereof.

36. (Original) The method of claim 35, wherein the vasoactive prostaglandin is selected from the group consisting of PGE₀, PGE₁, PGE₂, and the methyl, ethyl and isopropyl esters thereof.

37. (Original) The method of claim 32, wherein the vasoactive prostaglandin is selected from the group consisting of arboprostil, carbaprostacyclin, carboprost tromethamine, dinoprost tromethamine, dinoprostone, enprostil, iloprost, lipoprost, gemeprost, metenoprost, sulprostone, tiaprost, viprostil, viprostil methyl ester, 16,16-dimethyl-Δ²-PGE₁ methyl ester, 15-deoxy-16-hydroxy-16-methyl-PGE₁ methyl ester, 16,16-dimethyl-PGE₁, 11-deoxy-15-methyl-PGE₁, 16-methyl-18,18,19,19-tetrahydro-carbacyclin, 16(RS)-15-deoxy-16-hydroxy-16-methyl-PGE₁ methyl ester, (+)-4,5-didehydro-16-phenoxy-α-tetranor-PGE₂ methyl ester, 11-deoxy-11α,16,16-trimethyl-PGE₂, (+)-11α,16α,16β-dihydroxy-1,9-dioxo-1-(hydroxymethyl)-16-methyl-trans-prostene, 9-chloro-16,16-dimethyl-PGE₂, 16,16-dimethyl-PGE₂, 15(S)-15-methyl-PGE₂, 9-deoxy-9-methylene-16,16-dimethyl-PGE₂, potassium salt, 19(R)-hydroxy-PGE₂, 11-deoxy-16,16-dimethyl-PGE₂, and combinations thereof.

38. (Original) The method of claim 32, wherein the therapeutically effective amount of the vasodilator is in the range of approximately 1 to 5000 μg.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

39. **(Original)** The method of claim 38, wherein the therapeutically effective amount of the vasodilator is in the range of approximately 20 to 2000 μg .

43. **(Previously amended)** The method of claim 25, wherein administration of the second active agent is topical, transdermal, sublingual, intranasal, buccal, rectal, parenteral, or by inhalation.

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44. **(Original)** A method for enhancing sexual desire and responsiveness in a female individual, comprising orally administering to the individual, approximately 0.25 to 72 hours prior to sexual activity, a therapeutically effective amount of an orally active androgenic agent, followed by topical administration, approximately 0.25 to 24 hours prior to sexual activity, of a therapeutically effective amount of a prostaglandin.

45. **(Original)** The method of claim 44, wherein the prostaglandin is selected from PGE_0 , PGE_1 , PGE_2 , and hydrolyzable lower alkyl esters thereof.

46-49. **(Canceled)**

50. **(Previously amended)** A method for enhancing sexual desire and responsiveness in a female individual, comprising orally administering an orally active androgenic agent to the individual in an amount effective to provide a blood level of the agent or a metabolite thereof that approximates the blood level of the agent or a metabolite thereof during ovulation, wherein said administering is carried out on an as-needed basis.

51-54. **(Canceled)**

55. **(Currently canceled)**

56. **(Newly added)** A method for enhancing sexual desire and responsiveness in a female individual, comprising orally administering to the individual a therapeutically effective amount of: (a) an orally active androgenic agent as a first active agent; (b) a dopamine agonist or a serotonin agonist as a second active agent; and (c) a vasoactive agent as a third active agent, wherein administration is on an as-needed basis.

Attorney Docket No. 9050-0053
Serial No. 09/919,471

57. (Newly added) The method of claim 56, wherein the dopamine agonist is selected from the group consisting of levodopa, bromocriptine, pergolide, apomorphine, piribedil, pramipexole, ropinirole, and combinations thereof.

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58. (Newly added) The method of claim 56, wherein the serotonin agonist is selected from the group consisting of 2-methyl serotonin, buspirone, ipsaperone, tiaperone, gepirone, ergot alkaloids, 8-hydroxy-(2-N,N-dipropyl-amino)-tetraline, 1-(4-bromo-2,5-dimethoxyphenyl)-2-aminopropane, cisapride, sumatriptan, *m*-chlorophenylpiperazine, trazodone, zacopride, mezacopride, and combinations thereof.

59. (Newly added) A method for enhancing sexual desire and responsiveness in a female individual, comprising orally administering to the individual a therapeutically effective amount of: (a) an orally active androgenic agent as a first active agent; and (b) a vasoactive agent as a second active agent, wherein administration is on an as-needed basis.

60. (Newly added) The method of claim 56, wherein the vasoactive agent is a calcium channel blocker.

61. (Newly added) The method of claim 59, wherein the vasoactive agent is a calcium channel blocker.
